(b) When chemical substances enter the environment as a result of a proposed action or other regulatory alternatives, the portion of the EIS format on *environmental consequences* (40 CFR 1502.10(g)) will include discussion of the environmental fates and effects of those substances similar to that described in § 25.31a.

(c) Any final EIS will contain any additional information gathered by the agency after the publication of the draft EIS, a copy of or a summary of the comments received on the draft EIS, and the agency's responses to the comments as required in 40 CFR 1503, including any revisions resulting from comments or other information.

(d) Draft and final supplemental EIS's will conform to the EIS format (40 CFR 1502.10) unless there is a compelling reason to do otherwise.

Subpart D—Agency Decisionmaking

§ 25.40 Procedures for incorporating environmental considerations into agency decisionmaking.

(a) These procedures are to ensure that environmental information is provided to decisionmakers in a timely manner. The NEPA process is an integral part of FDA's decisionmaking. Agency decisionmakers ensure that the policies and purpose of NEPA and CEQ regulations are complied with by:

(1) Completing or assuring the completion of an EA, determining whether an EIS is required and, ordinarily, completing a draft EIS (if one is required) prior to or at the time of proposing an action subject to §§ 25.21 and 25.22.

(2) Including in decision documents and supporting environmental documents a discussion of all alternatives considered in the decision as required by 40 CFR 1502.14. Every action memorandum proposing an agency action included under § 25.21 or § 25.22 will contain an evaluation of the environmental impact of the proposed action and will be accompanied by a draft or final EIS if one is required.

(3) Submitting relevant environmental documents, comments, and responses with other decision documents through the review process.

(4) Including in the records of proceedings any appropriate environmental documents, comments, and responses.

(5) Completing and circulating a final EIS before the decision to implement an action that significantly affects the quality of the human environment.

(b) There are certain regulatory actions which, because of their immediate importance to the public health, make adherence to the requirements of the CEQ regulations and these regulations concerning minimum periods of public review impractical. Compliance with the requirements for environmental analysis under NEPA is impossible where emergency circumstances require immediate regulatory action to safeguard the public health. For such actions, the responsible agency official shall consult with the CEQ about alternative arrangements before the action is taken, or after the action is taken, if time does not permit prior consultation with CEQ.

(c) Certain FDA actions are subject to statutory time limits that sometimes do not provide sufficient time to complete the required environmental document. Should the responsible agency official be unable to complete environmental consideration of the proposed action before a notice of filing of a food or color additive petition is required to be published, and if the subsequent environmental analysis leads to the conclusion that no EIS is necessary, the FEDERAL REGISTER document publishing the final regulation rather than the notice of filing shall state that no EIS is necessary and that the FONSI and the EA are available upon request and filed in the FDA Dockets Management Branch. If it is concluded that an EIS is necessary, the final regulation, final EIS, and record of decision shall be made available as prescribed in 40 CFR 1506.10.

§ 25.41 Actions for which a finding of no significant impact and an environmental assessment are prepared.

(a) As required by 40 CFR 1501.4(e), a FONSI is prepared for an individual action or groups of related actions that will not significantly affect the quality